EXPRESS MAIL LABEL NO. EL740534444US

PATENT APPLICATION
Docket No. 2409.3273.3US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	Geoffrey S. Martin et al.	)	
For:	MULTIPLE LUMEN CATHETER	)	
Continuation Application of:		)	
Serial No.:	139,705	)	Group Art Unit 3262
Filing Date:	August 25, 1998	)	
Prior Examiner:	Ronald K. Stright, Jr.	)	

APPENDIX A TO PRELIMINARY AMENDMENT:
Detail of Amendments to Specification as Originally Filed

Box: PATENT APPLICATION
Commissioner for Patents
United States Patent and Trademark Office
Washington, D. C. 20231

Sir:

Prior to an examination on the merits, kindly amend the specification of the above-captioned continuation application as originally filed as indicated below:

Page 2, line 3, immediately before Paragraph No. [0001], insert and center the following heading:

--RELATED APPLICATIONS--

[0001] This application is a continuation application of copending United States Patent Application Serial No. [08/205,331] 139,705 that was filed on [03/03/94 which is a continuation of Application Serial No. 07/785,351 filed on 10/30/91 which is a continuation of Application Serial No. 07/288,364 filed on 12/22/88 and now U.S. Serial No. 5,195,962.] August 25, 1998 (hereinafter "the Parent Application"), and that issued as United States Patent No. 6,206,849 on March 27, 2001. The Parent Application is a continuation application of United States Patent Application Serial No. 481,169 that was filed on June 7, 1995 (hereinafter "the Grandparent Application"), and that issued as United States Patent No. 5,797,869 on August 25, 1998. The Grandparent Application is a continuation application of United States Patent Application Serial No. 205,331 that was filed on March 3, 1994 (hereinafter "the Great-Grandparent Application"), and that issued as United States Patent No. 5,472,417 on December 5, 1995. The Great-Grandparent Application is a continuation application of United States Patent Application Serial No. 785,351 that was filed on October 30, 1991 (hereinafter "the Great-Great-Grandparent Application"), and that is now abandoned. The Great-Great-Grandparent Application is a continuation application of United States Patent Application Serial No. 288,364 that was filed on December 27, 1988 (hereinafter "the Great-Great-Great-Grandparent Application"), and that issued as United States Patent Application No. 5,195,962 on March 23, 1993. This application is also related to United States Patent Application Serial No. 699,421 that was filed on May 31, 1991, as a divisional application of the Great-Great-Great-Grandparent Application, and that issued as United States Patent No. 5,135,599 on August 4, 1992.

Page 2, line 9, immediately before Paragraph No. [0002], delete the original heading and substitute centered therefor the following:

--BACKGROUND--

Page 2, lines 10-12, enhance Paragraph No. [0002] and subdivide as follows into two (2) paragraphs:

[0002] 1. Field of the Invention.

[0002.1] This invention relates to a multiple lumen catheter and more particularly to such a catheter for insertion into a vein of a patient to be used in haemodialysis treatments. The invention also relates to methods for manufacturing the multiple lumen catheter.

Page 2, line 14, immediately before Paragraph No. [0003], delete the original heading.

Page 2, lines 15-22, enhance Paragraph No. [0003] and subdivide as follows into two (2) paragraphs:

[0003] 2. Background Art.

[0003.1] Multiple lumen catheters have been available for many years for a variety of medical purposes. It is only in recent years, however, that such catheters have been developed for use in haemodialysis. The general form of multiple lumen catheters goes back to as early as 1882 when Pfarre patented such a catheter in the United States under Serial No. 256,590. This patent teaches a flexible dual lumen catheter which is used primarily for cleaning and drainage of, for

example, the bladder, rectum, stomach and ear. In this type of catheterization, the catheter is introduced into an existing body orifice without the use of any puncturing needle or guidewire.

Page 7, line 10, immediately before Paragraph No. [0017], delete the underlining in the original heading to produce the following:

--BRIEF DESCRIPTION OF THE DRAWINGS--

[0029] Fig. 16 is a perspective view of a plug for use in making yet another embodiment of the catheter; [and]

[0030] Fig. 17 is a sectional view of still another embodiment of the catheter and using a separate bonded tip;[.]

Page 9, line 1, immediately before Paragraph No. [0033] delete the underlining in the original heading and insert --DETAILED-- at the beginning of the heading to produce the following:

--DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS--

[0037] The IV tube 35 is terminated at its outer end in a luer lock fitting 39 for receiving a syringe or male luer lock connector.

[0040] As will be described in more detail with reference to subsequent views, the tube 35 is aligned with a central lumen to permit the Seldinger wire 21 to pass through the catheter. The

wires [exists at] exit distal end 28 of catheter body 26 through a tip aperture 64 at the apex of tip 29 which is essentially conical so that the catheter can slide over the wire and into the patient during insertion. The extraction and return tubes 32, 34 are linked at connector 30 with lumens in the body 26 to connect with respective groups of side apertures 44, 45 (some of which can be seen in this view) near the distal end of the catheter 28. As a result, when inserted and in use, blood can be removed and returned in a closed loop with a haemodialysis machine using the tubes 32, 34. Between treatments the tube 35 is available for intravenous infusion of liquid medicaments.

[0042] The extraction lumen 50 is blocked short of the tip 29 by a first insert 56 which is formed of polyurethane and bonded in place using a suitable solvent such as cyclohexanane, leaving a hollow extension A of extraction lumen 50 distal of first insert 56. Extraction apertures 44 are provided in the outer wall 46 of the cylindrical portion 26, just short of the insert 56, to permit blood to flow from the patient's vein into the extraction lumen 50 and thus through the connector 30 to the extraction tube 32 and the dialysis machine. It should be noted that the apertures 44 are conveniently circular but may be of any suitable shape or size including scaphoid. Also, further extraction apertures may be provided around the lumen 50 as required consistent with the aperture nearest the tip being immediately adjacent the insert 56 to minimize dead spaces.

[0043] The return lumen 52 is similarly blocked by a second insert 60 immediately adjacent the last of several return apertures 45. This last aperture is positioned closer to the tip 29 than is the last of the intake apertures 44 in the extraction lumen 50 to minimize the risk of cross flow as returning blood finds its way back into the lumen 50. A hollow extension B of return lumen 52

remains distal of second insert 60. Although some cross-flow is not critical, excess cross-flow will extend the time needed for haemodialysis.

[0046] Before shaping the tapered tip 29, the inserts 56, 60 are positioned and affixed in the respective lumens 50, 52 as shown in Fig. 3. The inserts are shaped to the cross-section of the lumens and affixed as previously described. A cylindrical wire 66 (shown in [chain dotted] chain-dotted outline), of corresponding diameter to that of the guide wire 21 (Fig. 2), is inserted through the IV lumen 54 to extend from the distal end of the tubing which is then located in a conical tapered mould 68 (shown in chain-dotted outline). The extrusion is heated by R.F. and as it softens it is pushed into the mould 68 in the direction of arrow D, such that the outer wall 46 and the septum 48 merge at the tip 29. The end of the body assumes a conical tapered shape with a radiused end and the material masses in the lumens 50, 52 forming ends 70, 72. The IV lumen 54 retains its internal shape because it is supported on the wire 66. The now tapered tip is cooled to some extent and then removed from the mould 68 and allowed to cool further and harden.

[0055] It will be seen in Fig. 10, that after the mandrels are engaged, the second sleeve 74 and contained portion of the extrusion are expanded to form connector 30 and, after completion, the appearance of connector 30 will be as shown in Fig. 11.

[0064] The tip structure shown in Fig. 3 can be made in a number of ways. An alternative is shown in Figs. 13 and 14. For ease of reference the reference numerals used in relation to these figures correspond to those used above prefixed with the numeral 1. The distal end 128 and tip 129

of a catheter has inserts 156, 160 which extend to fill the unused portions of the extraction and return lumens. The inserts are entered in the lumens 150, 152 and may be affixed therein by a solvent. When the end 128 is heated in the mould 168 the inserts 156, 160 are softened and deformed and the outer wall 146 collapses to merge with the septum 148. The leading ends of the inserts 156, 160 also merge with the septum 148, as represented by the ghost outlines in Figs. 13 and 14. The resulting catheter has an appearance similar to the catheter described above with a tip opening 164, but with a stiffer leading end.

[0067] Reference is now made to Fig. 16 to describe a moulded plug of polyurethane for use in making tips. This plug P has end pieces 200,202 shaped to fit snugly in the lumens 50, 52 (Fig. 3). The end pieces are attached to respective spacers 204,206 which depend from a hub 208 at respective weakened joints 210,212. The hub has a central opening 214 matching the third lumen 54 so that the wire used in moulding can be used to locate the hub centrally.

Page 19, line 19, through page 20, line 10, amend Paragraph No. [0068] and subdivide as follows into two (2) paragraphs:

[0068] The procedure, when using the plug P of Fig. 16, is to first bend the spacers 204,206 about the joints 210,212 so that the end pieces 200,202 come together for insertion in the end of the extruded body 26. The pieces are pushed home with solvent until the hub 208 meets the end of the body. The pieces 200,202 will then automatically be in the required positions controlled by the lengths of the spacers 204,206. Moulding then proceeds as before so that the hub and adjacent parts of the spacers will become integral portions of the tip.

[0068.1] A further embodiment is shown in Fig. 17. This structure includes a separate moulded tip 216 preferably of polyurethane, which is engaged in and bonded to the [end of the extrusion] distal end F of an extruded catheter body E. The tip 216 has an outer conical form and defines a central opening 218 [forming] at one end of a central passageway G that forms a continuation of the third lumen 220. A pair of extensions 222, 224 are shaped to fit in the respective lumens 226, 228 and have lengths to match the positions of the apertures 230,232 in the side wall of the lumens. The ends of the extensions are preferably shaped to meet the apertures and complement the natural flow patterns so that dead spaces will be minimized, if not eliminated.

[0069] The structure shown in Fig. 17 can also be partly formed by heating in a mould to blend the joint between the tip and the extrusion. This technique can also be used to [part form] form part of the assembly to improve the tip, if necessary.

DATED this 27th day of March, 2001.

Respectfully submitted,

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